



CASE WESTERN RESERVE UNIVERSITY

January 22, 2003

Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Mail Stop E-79
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I am writing in response to the Centers for Disease Control and Prevention's solicitation for comments on 42 CFR Part 73, Interim Final Rule, Possession, Use, and Transfer of Select Agents and Toxins published in the Federal Register, Vol. 240, No. 67 on Friday, December 13, 2002.

I strongly support the comments and recommendations for 42 CFR Part 73 submitted by the Howard Hughes Medical Institute (HHMI) on January 21, 2003. I have attached a copy of the HHMI "Comments on 42 CFR Part 73" for your reference. Specifically, the basis for my support and endorsement is that the recommendations will ensure the appropriate availability of biological agents and toxins for research, education, and other legitimate purposes and will make the safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin risk-based. These provisions are requirements of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Generally, the adoption of the recommendations of the HHMI will lessen the administrative burden of the Final Rule, allow for an effective performance-based security plan, and ensure the relevance of the Final Rule to the biomedical research environment. The changes suggested should increase, not decrease the security results that are a goal of the proposed rule and help to integrate the rules sensibly into existing regulatory structures. It is important that the rules do not compromise the ability to carry out necessary research on the agents of concern. If the rule contains administrative provisions that are vague or too burdensome to implement, they will simply block or greatly inhibit generation of critical scientific information on the agents of concern.

I appreciate the opportunity to comment on the Interim Final Rule and thank you for your consideration.

Sincerely,

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Enclosure: Comments on 42 CFR Part 73, Interim Final Rule
Possession, Use and Transfer of Select Agents and Toxins

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